

Claims

1. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:

a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

the filter body being at least partially of laminate construction comprising a membrane coated with a coating which is biocompatible, the thickness of the coating being from 4% to 40% of the thickness of the membrane to enhance the mechanical characteristics of the filter body.

2. A filter element as claimed in claim 1 wherein the thickness of the coating is from % to 30% of the thickness of the membrane.
3. A filter element as claimed in claim 1 or 2 wherein the thickness of the coating is approximately 20% of the thickness of the membrane.

- 5 4. A filter as claimed in any preceding claim wherein the membrane is of a material selected from one or more of polyether block amide (PEBAX), polyester, polyethylene, polyurethane, terephthalate, nylon or, as appropriate, copolymers thereof.
- 10 5. A filter element as claimed in any preceding claim wherein the coating is at least partially of a material selected from a non thrombogenic material and a fluropolymer material.
- 15 6. A filter element as claimed in any preceding claim wherein the coating is of a hydrophilic material.
7. A filter element as claimed in any of claims 1 to 6 wherein the coating is of a hydrogel material.
- 20 8. A filter element as claimed in any preceding claim wherein the coating includes a physiologically acceptable additive.
9. A filter element as claimed in claim 8 wherein the additive is a therapeutic additive.
- 25 10. A filter element as claimed in claim 8 or 9 wherein the additive is an antithrombogenic additive.
11. A filter element as claimed in claim 10 wherein the antithrombogenic additive is heparin.
- 30 12. A filter element as claimed in any preceding claim wherein the filter body is surface treated prior to application of the coating.

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- 5 13. A filter element as claimed in any preceding claim wherein the filter body comprises a proximal body section, a distal body section and an intermediate body section interconnecting the proximal and distal body sections, one or more of the body sections being of laminate construction.
14. A filter element as claimed in claim 13 wherein the body sections are of the same laminate construction.
- 10 15. A filter element as claimed in claim 14 wherein at least two of the body sections are of different laminate construction.
16. A filter element as claimed in any preceding claim wherein the filter body has regions of varying hardness or stiffness.
17. A filter element as claimed in any preceding claim wherein the filter body has a durometer of between 60D and 70A Shore hardness.
- 20 18. A filter element as claimed in any preceding claim wherein the filter body has a first relatively stiff portion and a second relatively soft portion.
19. A filter element as claimed in any preceding claim wherein one portion or section of the filter body has a larger wall thickness than the wall thickness of another section or portion.
- 25 20. A filter element as claimed in any preceding claim wherein the filter body comprises a proximal body section and a distal body section, one of which forms a stiff first portion and the other of which forms a soft second portion.
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21. A filter element as claimed in claim 20 wherein a proximal body section forms the soft second portion.
  22. A filter element as claimed in any of claims 18 to 21 wherein the filter body comprises a proximal body section and a distal body section interconnected by an intermediate body section, one or both of the proximal body section and the intermediate body section forming the soft second portion, the distal body section forming the stiff first portion.
  23. A filter element as claimed in any preceding claim wherein the proximal body section has a ribbed outer surface.
  24. A filter element as claimed in any preceding claim wherein a plurality of spaced-apart longitudinal ribs are provided on the proximal section.
  25. A filter element as claimed in any preceding claim wherein the proximal body section includes corrugations.
  26. A filter element as claimed in any preceding claim wherein the filter body has expansion means to facilitate retrieval of the captured embolic material.
  27. A filter element as claimed in claim 26 wherein at least the distal portion of the filter body is of a membrane material that is stretchable.
  28. A filter element as claimed in claim 27 wherein at least the membrane is stretchable in the longitudinal direction to facilitate retrieval from the vasculature.

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29. A filter element as claimed in any of preceding wherein the filter body includes an intermediate portion extending proximally of the distal portion, the intermediate portion being of a membrane material that is stretchable.

30. A filter element as claimed in any preceding claim wherein the filter body is a membrane of a memory material.

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31. A filter element as claimed in claim 30 wherein the membrane is of polymeric material.

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32. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:

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a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

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a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

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a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

the filter body having regions of varying hardness or stiffness.

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33. A filter element as claimed in claim 32 wherein the filter body has a durometer of between 60D and 70A Shore hardness.
34. A filter element as claimed in claim 32 or 33 wherein the filter body has a first relatively stiff portion and a second relatively soft portion.
35. A filter element as claimed in claim 34 wherein the first portion has a larger wall thickness than the wall thickness of the second portion.
36. A filter element as claimed in claims 34 or 35 wherein the filter body comprises a proximal body section and a distal body section, one of which forms said stiff first portion and the other forming the soft second portion.
37. A filter element as claimed in claim 36 wherein the proximal body section forms the soft second portion.
38. A filter element as claimed in any of claims 34 to 37 wherein the filter body comprises a proximal body section and a distal body section interconnected by an intermediate body section, one or both of the proximal body section and the intermediate body section forming the soft second portion, the distal body section forming the stiff first portion.
39. A filter element as claimed in any of claims 36 to 38 wherein the proximal body section has a ribbed outer surface.
40. A filter element as claimed in any of claims 36 to 39 wherein a plurality of spaced-apart longitudinal ribs are provided on the proximal section.
41. A filter element as claimed in any of claims 36 to 40 wherein the proximal body section includes corrugations.

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42. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:

5 a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

10 a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

15 a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

20 wherein of the filter body has expansion means to facilitate retrieval of captured embolic material.

43. A filter element as claimed in claim 42 wherein at least the distal portion of the filter body is of a membrane material that is stretchable.

25 44. A filter element as claimed in claim 43 wherein at least the membrane is stretchable in the longitudinal direction for retrieval from the vasculature.

45. A filter element as claimed in any of claims 42 to 44 wherein the filter body includes an intermediate portion extending from the distal portion, the intermediate portion being of a membrane material that is stretchable.

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46. A filter element as claimed in any of claims 43 to 45 wherein the membrane is of a memory material.

5 47. A filter element as claimed in claim 46 wherein the membrane is of polymeric material.

48. A transcatheter embolic protection device including:

10 a delivery system comprising:

a tubular member having a longitudinal axis, distal and proximal portions, said distal portion of the tubular member being removably advanceable into the vasculature of a patient;

15 a medical guidewire longitudinally axially movable in said tubular member and having distal and proximal portions;

20 and a filter element as claimed in any preceding claim, the filter body having;

a first collapsed, insertion and withdrawal configuration and a second expanded, deployed configuration;

25 a proximal inlet section and a distal outlet section, said proximal inlet section including inlet openings which are operable to admit body fluid when the filter body is in the second expanded configuration;



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a plurality of outlet openings disposed on at least a portion of the filter element adjacent to the distal outlet section;

wherein said filter body is moved between said first and second configurations by displacement of said delivery system.

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49. A device of claim 48 wherein the filter body has collapsible filter frame operably coupled thereto.
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50. A device as claimed in claim 49 wherein said frame comprises a plurality of support arms having proximal and distal ends.
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51. A device of claim 50 wherein the arms are formed of an elastic, a superelastic and/or a shape memory material.
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52. A device of any of claims 49 to 51 wherein said frame is constructed such that filter body is biased toward said second, deployed configuration.
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53. A device of any of claims 50 to 52 wherein said inlet openings are defined at least partially by said arms.
54. A device of any of claims 50 to 52 wherein proximal portions of said arms extend generally outwardly and distally from said guidewire when said filter body is in said second, deployed configuration.
55. A device of any of claims 50 to 54 wherein distal portions of said arms extend generally outwardly and proximally from said guidewire when said filter body is in said second, deployed configuration.

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56. A device of any of claims 48 to 55 wherein the distal portion of the tubular member further includes a pod for receiving therein the filter body when in said first, collapsed configuration.
57. A device of claim 56 wherein said filter body is urged into said first, collapsed configuration by said pod when the guidewire is moved proximally.
58. A device of any of claims 48 to 57 wherein said guidewire is solid.
59. A device of any of claims 48 to 58 wherein said filter body comprises a sleeve slidably disposed on said guidewire.
60. A device of claim 59 further comprising stops for limiting the range of longitudinal movement of the sleeve on said guidewire.
61. A device of claim 60 wherein the sleeve further comprises a guidewire member distal to the filter body tapering distally.

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57. A device of claim 56 wherein said filter body is urged into said first, collapsed configuration by said pod when the guidewire is moved proximally.

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58. A device of any of claims 48 to 57 wherein said guidewire is solid.

59. A device of any of claims 48 to 58 wherein said filter body comprises a sleeve slidably disposed on said guidewire.

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60. A device of claim 59 further comprising stops for limiting the range of longitudinal movement of the sleeve on said guidewire.

61. A device of claim 60 wherein the sleeve further comprises a guidewire member distal to the filter body tapering distally.